Before the FEDERAL COMMUNICATIONS COMMISSION WASHINGTON, D.C. 20554

In the Matter of)	
Investigation of the Spectrum Requirements for Advanced Medical Technologies))	ET Docket No. 06-135
Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service)))	RM-11271
at 401-402 and 405-406 MHz))	ET Docket No. 05-213
DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications)	ET Docket No. 03-92
Service Rules)	ET Docket No. 05 52
Biotronik, Inc. Request for Waiver of		
the Frequency Monitoring		
Requirements for the Medical Implant		
Communications Service Rules		

REPLY COMMENTS OF ORBCOMM INC.

Pursuant to Sections 1.415 and 1.419 of the Commission's Rules, 47 C.F.R. §§ 1.415, 1.419, ORBCOMM Inc. ("ORBCOMM") hereby submits reply comments with regard to the Commission's Notice of Proposed Rulemaking in this proceeding. As explained in greater detail below, as a general matter ORBCOMM has no objection to the proposal to allocate spectrum for new types of wireless medical devices operating in the 401-406 MHz band, and

Investigation of the Spectrum Requirements for Advanced Medical Technologies, FCC 06-103, released July 18, 2006; Federal Register Vol. 71 p. 43682 (August 2, 2006)(hereafter cited as "NPRM").

observes that the initial commenters generally supported the Commission's proposals. ORBCOMM simply wants to ensure that in allocating the spectrum for such services the Commission does not cause interference to or constrain the downlink operations of the Non-Voice, Non-Geostationary Mobile Satellite Service (NVNG MSS or Little LEO) operating in the adjacent 400-401 MHz band. In addition, to the extent that some commenters urged that the Commission allocate even more spectrum, ORBCOMM wants to ensure that the adjacent spectrum in the 400-401 MHz band is not considered as a candidate for any such additional allocation.

ORBCOMM is a global satellite data communications company that provides reliable, cost-effective data communications services to customers around the world through its unique low-earth orbit ("LEO") satellite network and global ground infrastructure. ORBCOMM currently is the sole Commission-licensee in the NVNG MSS.² ORBCOMM provides service via its constellation of satellites, and presently operates in the VHF and UHF bands. A diverse customer base uses ORBCOMM services to track, monitor and control mobile and fixed assets, including trucks, containers, marine vessels, locomotives, heavy machinery, pipelines, oil wells, utility meters and storage tanks anywhere in the world.

Of particular relevance to this proceeding, ORBCOMM is currently using the 400-400.15 MHz band for timing downlinks, and other portions of

Orbital Communications Corporation, 9 FCC Rcd 6476 (1994).

or the 400.15-401 MHz band have been allocated to the NVNG MSS.³
ORBCOMM thus has a strong interest in the proposed adjacent-band operations that are the subject of this *NPRM*.⁴ As such, ORBCOMM wants to ensure that the wireless medical devices will not cause harmful interference to its current and potential future downlink operations in the 400-401 MHz band. In addition, ORBCOMM does not believe that any additional constraints – beyond the current out-of-band emissions limits – should be applied to the NVNG MSS downlinks in the 400-401 MHz band. Finally, to the extent that two commenters seek additional spectrum, the Commission should not consider the 400-401 MHz band as a candidate for such an allocation.

Protection of ORBCOMM

As one tenet of its spectrum policy, the Commission relies on radio licensees to act as "good neighbors" – by operating within their frequencies and their service areas, the licensees avoid causing harmful interference to

³ See, 47 C.F.R. § 25.202(a)(3).

The Commission acknowledges that interference with other in-band services is an issue in this proceeding, *NPRM* at n. 46, but does not therein mention adjacent band operations (such as Little LEO downlinks). The *NPRM* at ¶ 22 discusses adjacent services operating above the upper end of the 401-406 MHz band, but does not address the services operating adjacent to the lower end of the band. ORBCOMM is submitting these comments to ensure that the NVNG MSS downlinks are factored into the Commission's analysis in this proceeding.

licensees in adjacent territories and frequencies.⁵ Part of that policy is the creation of compatible "neighborhoods" where the adjacent frequency bands are occupied by services with similar characteristics. ORBCOMM believes that NVNG MSS downlinks and the proposed new wireless medical devices can be good neighbors, but the Commission should adopt technical specifications for this service to ensure such an outcome.

In the *NPRM* the Commission acknowledges that one of the objectives in establishing the Medical Implant Communication Service (MICS) was to avoid interference to other services.⁶ Indeed, the great majority of the types of medical devices at issue here under current rules operate on an unlicensed basis,⁷ which requires the devices to operate without causing interference to other services. In order to minimize the risk of harmful interference, these current devices are restricted to a very low maximum EIRP of 25 microwatts.⁸ In this proceeding, the Commission proposes similar very strict limits on the new devices that would operate in the 401-402 and 405-406 MHz bands:

Specifically, we propose to allow medical implant or body-worn devices and associated control station devices that operate without frequency

⁵ Spectrum Policy Task Force Report, ET Docket No. 02- 135 (November 2002) at p. 22. See also, Robert Frost, "Mending Wall" ("Good fences make good neighbors").

⁶ NPRM at ¶ 7.

⁷ NPRM at ¶ 9.

Id.

monitoring to operate at 401-402 MHz and 405-406 MHz, and to limit such devices to an EIRP that does not exceed 250 nanowatts (nW) and a duty cycle that does not exceed 0.1% during any one-hour interval.⁹

In addition, the Commission has proposed limits on the out-of-band emissions that can be produced by the contemplated devices, which also protects against harmful interference to neighbors such as ORBCOMM:

The Medtronic petition suggests a standard by which emissions more than 50 kHz away from the fundamental emission would need to be attenuated by at least 20 dB; and emissions outside of the designated bands would need to be attenuated to 200 $\mu\text{V/m}$ at 3 meters in the frequency ranges 216-400.9 MHz and 406-960 MHz. This is similar to the rules adopted for MICS transmitters, except that the field strength limit of 200 $\mu\text{V/m}$ at 3 meters would have to be achieved in within a narrower 100 kHz span (400.9-401 MHz), instead of the 250 kHz span under the MICS rules. 10

ORBCOMM believes that if such power level restrictions and duty cycle limits are imposed on the new devices that will operate in the 401-402 MHz band, and if the Commission also adopts the out-of-band emission limits

NPRM at ¶ 25. In its petition for rulemaking, Biotronik had suggested a somewhat lower power limit of 100 nW eirp and a similar duty cycle of 0.1% per hour. NPRM at ¶ 19. There is some ambiguity as to whether the Commission is considering any higher limits than the 250 nW discussed in the NPRM. The NPRM also discusses the possibility of "monitoring outside of clinic environments." NPRM at ¶ 17. It is not clear whether any such devices would operate at a higher power level than the strict limits suggested in the NPRM. To the extent the Commission considers any such higher power devices, ORBCOMM suggests that these operations take place away from the edges of the band so as to minimize risk of interference to adjacent band services such as ORBCOMM's. Cf., NPRM at ¶ 26 (seeking comments on alternative designs for the 401-406 MHz band).

¹⁰ *NPRM* at n. 48.

suggested in the *NPRM*, then these new devices are unlikely to cause harmful interference to ORBCOMM's operations in the adjacent band.

ORBCOMM would have to reassess its analysis, however, if the Commission decides to consider more lax requirements.

Absence of Added Constraints on ORBCOMM

As a "good neighbor," ORBCOMM has built and will continue to deploy satellites that comply fully with the current limits on power levels and out-of-band emissions. As a practical matter, the NVNG MSS satellites operate at relatively low power levels, because otherwise these global systems would have to engage in country-by-country coordination of their downlinks if the power flux-density produced by the space stations exceeds -125 dB(W/m²/4kHz) at the Earth's surface. Moreover, the Commission's Rules incorporate longstanding out-of-band emission limits for satellite services. ORBCOMM does not believe that any additional protections need to be afforded to these new wireless medical devices.

See, In the Matter of Amendment of Section 2.106 of the Commission's Rules to Allocate Spectrum to the Fixed-Satellite Service and the Mobile-Satellite Service for Low-Earth Orbit Satellites, 8 FCC Rcd 1812 (1993) at ¶ 14 and App. A at n. 647X.

¹² 47 C.F.R. § 25.202(f).

Most of the wireless medical devices under the current Rules operate under Part 15 on an unlicensed basis. As such, there is no expectation of protection from other licensed services. Rather, the wireless medical devices should be designed in such a manner as to tolerate operating in an environment where other devices and services are transmitting. Indeed, the NPRM acknowledges that:

[M]edical device manufacturers should be cognizant of the potential health and safety risks that could arise if implanted or body-worn medical radiocommunication devices are subjected to various levels of RF interference in a dynamic and unpredictable RF environment, and design their products with appropriate safeguards and robustness as is appropriate to their function. 14

One of the components of that "dynamic and unpredictable RF environment" for the proposed operations in the 401-402 MHz band will be the NVNG MSS downlinks operating immediately adjacent in the 400-401 MHz band.

Manufacturers must take these operations into account in designing new wireless medical devices that will operate in the 401-402 MHz band.

As noted above, ORBCOMM already operates under strict limits on power and out-of-band emissions. ORBCOMM does not believe that any further limits on its satellite downlinks are necessary or appropriate in order to accommodate the proposed changes to the allocation of the 401-402 MHz band. While there are numerous predictions of the likely benefits of these

¹³ NPRM at ¶ 9.

NPRM at ¶ 29 (emphasis added).

new wireless medical devices, the public interest benefits of the NVNG MSS have already been clearly demonstrated by ORBCOMM's provision of service over the last decade. Thus, in implementing these new medical offerings, the Commission should do so in a manner that would not adversely affect NVNG MSS.

<u>Additional Spectrum for Advanced Medical Technologies</u>

Two of the commenters – GE Healthcare and The Alfred Mann

Foundation – urged the Commission to allocate even more spectrum for advanced medical technologies. Both GE Healthcare and The Alfred Mann

Foundation claimed that the Commission should allocate even more spectrum than the two additional megahertz proposed to be allocated for advanced medical devices in this proceeding. ORBCOMM is not in a position to evaluate whether such additional spectrum is necessary. However, to the extent the Commission believes that more frequencies should be allocated for advanced wireless medical devices, the Commission should not reallocate the adjacent 400-401 MHz band for such purposes.

As explained above, this spectrum is allocated, *inter alia*, for NVNG MSS. The NVNG MSS provides numerous beneficial services that improve communications, enhance efficiency and support homeland security. Thus, it would be contrary to the public interest to take spectrum away from NVNG MSS. Moreover, the 400-401 MHz band is also used presently for Department of Defense and Meteorological satellite services. Even though this band is adjacent

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GE Healthcare Comments at pp. 7-14; The Alfred Mann Foundation Comments at pp. 10-14.

to the spectrum the Commission is currently proposing to allocate for new advanced wireless medical devices spectrum, it would not be a good candidate for any expansion needs for such a service.

In sum, as explained above, ORBCOMM believes the public interest would best be served by ensuring that the proposed new advanced wireless medical device service not constrain or supplant the NVNG MSS operations in the adjacent 400-401 MHz band.

Respectfully submitted,

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